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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,887	04/06/2005	Vladimir Velebny	074047.2	6569

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
09/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,887	VELEBNY ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-30 and 32-39* is/are pending in the application.

4a) Of the above claim(s) *6-26 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,27-30,32-37 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/05/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 22, 2009 has been entered.

Applicants' arguments, filed December 22, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Declaration

Applicant has submitted a Declaration under 37 C.F.R. 1.132 by the inventors of the invention, Vladimir Velebny, Lubos Sobotka, Stanislav Pavek, and Jana Ruzickova on December 22, 2009. This declaration has been fully considered however is not persuasive to overcome the rejection of record in the previous office action. Reasons of which are discussed in detail below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 27-30 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drizen et al. (US 2002/0037319 A1) in view of Cantor et al. (US 20030054025 A1), each already of record on pages 3-7 of the final office action dated July 07, 2009 the reasons of which are herein incorporated by reference.

Applicant has not amended claims 1-4, 27-30 or 32-37, thus the claims remain the same as they were in the final rejection referenced above. Applicant has submitted a declaration by the inventors and argues that the graph (Enclosure I) shows that hyaluronic acid (HA) molecular weight above 200,000 is better for wound healing, and

applicant argues that based on their graph that hyaluronan having a molecular weight higher than about 800,000 to 900,000 has practically the same healing speed. Applicant also notes that their graph does not go beyond 1,500,000 but states that "we know, based on pre-clinical and clinical tests that hyaluronan having molecular weight up to 2,500,000 acts practically the same as hyaluronan having a molecular weight of about 1,500,000 which is the final point in the graph" This argument is confusing, as it is not clear what point in the prior art applicant is trying to overcome with this argument. The graph (enclosure I) clearly shows an gradual increase after 870,000 and applicant's arguments that they know that 2,500,000 is the same is a statement without any factual support, but even if it were taken it is not clear what applicant thinks that this shows in regards to overcoming the prior art as all of claims 1-4, 27-30 and 32-37 have a lower limit of 200,000 and read upon the prior art of Drizen et al.

Applicant has also argued that no one produces a preparation of iodine and any other substance because PVP-iodine is much better than iodine and iodine and that applicant believes this is clear proof that one of skill in the art would choose PVP-Iodide rather than iodine and iodide. Firstly, the examiner disagrees with this statement as there are patents and applications based on combining iodine with other substances, see Cantor et al. (cited in this rejection) which teaches iodine complexes with potassium iodide (page 5, [0048]). Applicant points to a reference previously presented Shelanski et al. from 1956 which stated that PVP-iodine was less toxic than the iodine of Lugol's solution (page 728, second paragraph). It's not clear from the reference what is contained in the iodine of Lugol's solution or if it would be an iodine/iodide complex like

applicant claims and is taught in the prior art, but the fact that an author in 1956 thought PVP-Iodine was better than other available solutions is not evidence that nobody in the art would use this. Further, the examiner points to Cantor et al., who in 2003 (the year before applicant's filing date), teaches using Iodine/iodide as a wound healing composition is proof that it was in fact being used and considered in the art for that purpose despite what an author in 1956 thought of the composition. Also, it is noted that Cantor et al. teaches both iodine/iodide and PVP-iodine as options with no teaching that PVP-iodine is better and thus providing proof that this complex was not considered so obsolete as applicant alleges.

Applicant also argues unexpected results by pointing to enclosures II and III which compare HA with HA+ KI3. The fact that two wound healing substances is better than one is not unexpected and applicant has not compared their composition to the closest prior art which is HA and KI3 separately. Since potassium triiodide (or any iodine/iodide complex) has not been tested alone there is no way for one of ordinary skill in the art to determine if there is a greater than additive effect.

Applicant's declaration and arguments were very carefully considered however they are not deemed persuasive and this rejection is **MAINTAINED.**

Claims 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drizen et al. (US 2002/0037319 A1) in view of Cantor et al. (US 20030054025 A1), each already of record on pages 3-7 of the final office action dated July 07, 2009 the reasons of which are herein incorporated by reference, in further view of Miyata et al. (US

2002/0098244 A1, already of record in the office action dated October 16, 2008 the reasons of which are herein incorporated by reference.

Applicant has added a new claim 39, which further limits the molecular weight of the HA from about 1,000,000 to about 2,500,000. Applicant has argued that since Drizen et al. teaches 800,000 or less that this is unobvious over Drizen in view of Cantor. The term “about” is a relative term and one or ordinary skill in the art might consider 800,000 to be "about 1,000,000" after all it is much closer to that than it is to 1 or 3 trillion. However, it was also known in the art to use HA with higher molecular weights for wound healing compositions. Miyata et al., which was already of record in the non-final rejection of October 16, 2008 teaches 2,000,000 as a preferred molecular weight in their example 1 (page 5, [0083]) and they teach their sodium hyaluronate to be used as wound dressing [0070]. Thus it would have been obvious to one of ordinary skill in the art that even molecular weights as high as 2,000,000 are known in the art for this purpose and it would be well within the limits of routine optimization for one of ordinary skill in the art at the time of the invention to determine what molecular weight would work best for the individual patient and composition. Thus claim 39 is unpatentable over Drizen et al. in view of Cantor et al. in further view of Miyata et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Primary Examiner, Art Unit 1614